K060805 Page 1 of 2

ATTACHMENT 6-1

510(K) SUMMARY

MAY 24 2006

RAPID® 4 (for Given® Diagnostic System)

510(k) Number K_____

Applicant's Name:

Given Imaging Ltd.
Hermon Building (Shaar Yoqneam)
New Industrial Zone
P.O. Box 258
Yoqneam 20692, Israel
Tel.: 011-972-4-9097730
Fax: 011-972-4-9592466

Contact Person:

Shosh Friedman, RAC
Senior V.P. Regulatory & Clinical Affairs
Tel: 011-972-4- 9097784
Fax: 011-972-4-9938060
Email: shosh@givenimaging.com

Trade Name:

RAPID*Access* (for Given® Diagnostic System)

Classification Name:

Ingestible Telemetric Gastrointestinal/Esophageal Capsule Imaging System

Classification:

FDA has classified Ingestible Telemetric Gastrointestinal/Esophageal Capsule Imaging System as class II devices (product code 78NZE for small bowel and 78 NSI for esophageal capsule, regulation no. 876.1300) and they are reviewed by the Gastroenterology Panel.

Predicate Device:

- Given® Diagnostic System (with M2A®/PillCam™ SB Capsule) cleared for marketing under K010312, K020341, K022362, K022980, K031033, K032405, K040248 and K052184.
- Given® Diagnostic System with PillCam™ ESO Capsule cleared under K041149 and K042960

Performance Standards and Special Controls:

The Given® Diagnostic System complies with the requirements presented in "Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System: Final Guidance for Industry and FDA" issued on November 28, 2001

Intended Use:

There is no change in the intended used of the Given® Diagnostic System as a result of including the RAPID*Access optional accessory system*

Device Description:

The Given® Diagnostic System is comprised of three subsystems: PillCam™ Capsule (ESO or SB), Data Recorder Set, and RAPID® Workstation.

The RAPID*Access* optional accessory system, which is the subject of this Special 510(k) application, is designed to facilitate access to PillCam Capsule Endoscopy by allowing the performance of CE procedure without requiring the use of a full Given® Diagnostic System. It comes in two versions: RAPID*Access* RT (Real-Time), which is a standalone accessory that also allows monitoring the advancement of the capsule through the GI tract, and RAPID*Access SW* (software application).

Substantial Equivalence:

Given Imaging Ltd. believes that the Given® Diagnostic System with the RAPID*Access* optional accessory system is substantially equivalent to the market-cleared Given® Diagnostic System without raising any new safety and/or efficacy issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 24 2006

Shoshana Friedman, R.A.C.
Senior Vice President
Regulatory and Clinical Affairs
Given® Imaging Limited
New Industrial Park
P.O. Box 258, Yoqneam
ISRAEL 20692

Re: K060805
Trade/Device Name: Given® Diagnostic System – RAPID *Access*
Regulation Number: 21 CFR §876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NEZ and NSI
Dated: April 26, 2006
Received: April 28, 2006

Dear Ms. Friedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 6-3

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060805

Device Name:

Given® Diagnostic System

Indications for Use:

with PillCam™ SB Capsule

The Given® Diagnostic System with the PillCam™ SB Capsule is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from 10 years of age and up

The Suspected Blood Indicator (SBI) feature is intended to mark frames of the video suspected of containing blood or red areas

with PillCam™ ESO Capsule

The Given® Diagnostic System with the PillCam™ ESO Capsule is intended for the visualization of esophageal mucosa.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060805